Attorney Docket No. 224397 Client Reference No. E-116-2001/0-US-14

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Shanker Lal Gupta

Group Art Unit: Unassigned

Application No. Unassigned

Examiner: Unassigned

Filed: Herewith

For: FO

FORMULATION OF BORONIC ACID

COMPOUNDS

INFORMATION DISCLOSURE STATEMENT

Mail Stop Patent Application Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

within any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date

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		st Office Action on the merits; or (d) before the mailing of a first Office Action the filing of a request for continued examination under 37 CFR 1.114.
	37 CFI	(a), (b), (c) or (d) above, but before the mailing date of a final action under R 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that rise closes prosecution in the application, and includes <i>one</i> of:
		the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).
	or	the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).
	under and or 37 CF	the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance 37 CFR 1.311, or an action that otherwise closes prosecution in the application, nor before payment of the issue fee, and includes the Statement under R 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as th in 37 CFR 1.17(p) (see "Fees" below).
	payme contain 37 CF \$180 a NOTE: May 29	the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before ant of the issue fee, and within thirty days of receiving each item of information need in the Information Disclosure Statement, and includes the Statement under R 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of its set forth in 37 CFR 1.17(p) (see "Fees" below). This is for original applications except applications for a design patent, filed on or after a 2000, wherein a paper containing only an Information Disclosure Statement in compliance CFR 1.97 and 1.98 is being filed.
Copie	s of the	References
	Attach relevar an Eng action degree	s of the references listed on the enclosed Form 1449 are enclosed herewith, led to each reference not in the English language is a concise explanation of the ence pursuant to 37 CFR 1.98(a)(3). An English-language equivalent/patent, or glish-language abstract, or an English-language version of the search report or by a foreign patent office in a counterpart foreign application indicating the of relevance found by the foreign office is being submitted in lieu of a concise lation of the relevance pursuant to 37 CFR 1.98(a)(3).
	A cop	y of the foreign search report is enclosed herewith.
	parent furnish submi The I accord Proced relied	eferences listed on the enclosed Form 1449 were previously identified in the application(s) of the present application, and copies of the references were need at that time. Accordingly, additional copies of the references are not ted herewith, so as not to burden the file with duplicate copies of references. Examiner is respectfully requested to carefully review the references in lance with the requirements set out in the Manual of Patent Examining dure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) upon for an earlier filing date under 35 USC 120 in which copies of the nees were previously furnished are set out below:

U.S. APPL	ICATIONS	St	atus (check o	ne)
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1. 10/056,567	January 25, 2002		X	
2. 10/056,563	January 25, 2002		X	
3.				

Statement under 37 CFR 1.97(e) The undersigned hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement. The undersigned hereby states that no item of information contained in the

The undersigned hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

Statement under 37 CFR 1.704(d)

The undersigned hereby states that each item of information contained in the
Information Disclosure Statement was cited in a communication from a foreign patent
office in a counterpart application and that this communication was not received by
any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing
of the Information Disclosure Statement.

Fees

\boxtimes	No fee is owed by the applicant(s).
\Box	The IDS Fee of \$180 under 37 CFR 1.17(p) is enclosed herewith.

Method of Payment of Fees

Attached is a check in the amount of \$	
Charge Deposit Account No. 12-1216 in the amount of \$. (A duplicate copy of
this communication is enclosed for that purpose.)	

Authorization to Charge Additional Fees

If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

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Instructions as to Overpayment

Credit Account No. 12-1216. Refund

John Kilyk, Jr., Reg. No. 30 763 LEYDIG, VOIT & MAYER, LTD. Two Prudential Plaza, Suite 4900 180 North Stetson

Chicago, Illinois 60601-6780 (312) 616-5600 (telephone)

(312) 616-5700 (facsimile)

Date: September 18, 2003

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Substitute for form 1449A/B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known				
Application Number	Unassigned			
Filing Date	Herewith			
First Named Inventor	Shanker Lal GUPTA			
Group Art Unit	Unassigned			
Examiner Name	Unassigned			
Attorney Docket Number	224397			

				U.S. PATENT DOCUMENTS		
		U.S. Patent Do	cument			
Examiner Initials	Doc. No.	Application or Patent Number	Kind Code	Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
	AA	4,499,082		Shenvi et al.	2/12/85	
	AB	5,106,948		Kinder et al.	4/21/92	
	AC	5,169,841	1	Kleeman et al.	12/8/92	
	AD	5,187,157	1	Kettner et al.	2/16/93	
	ΑE	5,242,904		Kettner et al.	9/7/93	
	AF	5,250,720	7	Kettner et al.	10/5/93	
	AG	5,492,900		LaHann	2/20/96	
	AH	5,574,017	T	Gutheil	11/12/96	
	AI	5,780,454		Adams et al.	7/14/98	
	AJ	5,935,944		LaHann	8/10/99	
	AK	5,990,083		lqbal et al.	11/23/99	
	AL	6,066,730		Adams et al.	5/23/00	
	AM	6,083,903		Adams et al.	7/4/00	
	AN	6,619,076		Shull et al.	1/2/01	
	AO	6,297,217		Adams et al.	10/2/01	
	AP	2002/0169114	A1	Gupta	11/14/02	
	AQ	2002/0188100	A1	Plamondon et al.	12/12/02	

	FOREIGN PATENT DOCUMENTS							
		Foreign Patent Document				Translation		
Examiner Initials	Doc. No.	Office	Application or Patent Number	Kind Code	Name of Patentee or Applicant	Date of Publication	Yes	No*+
	AR	wo	98/35691	A1	Proscript, Inc.	8/20/98		
	AS	wo	99/15183	A1	Proscript Inc.	4/1/99		
	AT	wo	00/57887	A1	Glycosyn Pharmaceuticals, Inc.	10/5/00		
	ΑÜ	wo	01/02424	A2	DuPont Pharmaceuticals Co.	1/11/01		
	ΑV	wo	02/059130	A1	U.S. Government	1/8/02	_	
	AW	wo	02/059131	A1	Millennium Pharmaceuticals, Inc.	8/1/02	_	

		OTHER - NON PATENT LITERATURE DOCUMENTS			
Evaminer	Doc. Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item			Translation	
Examiner Initials	No. (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.				
	AX	CIECHANOVER, "The Ubiquitin-Proteasome Proteolytic Pathway," Cell, Vol. 79, pp. 13-21 (October 7, 1994)			
	AY	GENNARO, "Remington: The Science and Practice of Pharmacy," 20 th Edition, Chapter 42, pp. 802-803 (2000)			

Examiner Signature	Date Considered	
		l l

^{*} A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

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Please type a plus sign (+) inside this box ->	H	

Complet if Known Substitute for form 1449A/B/PTO **Application Number** Unassigned Herewith Filing Date **INFORMATION DISCLOSURE** Shanker Lal GUPTA First Named Inventor STATEMENT BY APPLICANT Unassigned **Group Art Unit** Unassigned **Examiner Name** (Use as many sheets as necessary) Attorney Docket Number 224397 2 Sheet

	OTHER - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (be				
Examiner Initials	Doc. No.	magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Yes	slation No*1	
	ΑZ	Kataoka et al., "Totally Synthetic Polymer Gels Responding to External Glucose Concentration: Their Preparation and Application to On-Off Regulations of Insulin Release," <i>J. Am. Chem. Soc.</i> , 120:12694-12695 (1998)			
	ВА	KIBBE, "Handbook of Pharmaceutical Excipients," 3 rd Edition, pp. 324-328 (2000)			
	ВВ	KORCEK et al., "Absolute Rate Constants for the Autoxidation of Organometallic Compounds, Part II. Benzylboranes and 1-Phenylethylboranes," <i>J. Chem. Soc., Perkin Trans.</i> II, pp. 242-248 (1972)			
	ВС	RICHARDSON et al., "A Phase 2 Study of Bortezomib in Relapsed, Refractory Myeloma," N. Engl. J. Med., Vol. 348, No. 26, pp. 2609-2617 (June 2003)			
	BD	SNYDER et al., "Aryl Boronic Acids. II. Aryl Boronic Anhydrides and their Amine Complexes," <i>J. Am. Chem. Soc.</i> , 80, pp. 3611-3615 (1958)			
	BE	STELLA et al., "Development of Parenteral Formulations of Experimental Cytoxic Agents. I. Rhizoxin (NSC-332598)," <i>International Journal of Pharmaceutics</i> , Vol. 43, pp. 191-199 (1988)			
	BF	WILLIAMS et al., "The Effects of Cooling Rate on Solid Phase Transitions and Associated Vial Breakage Occurring in Frozen Mannitol Solutions," <i>Journal of Parenteral Science & Technology</i> , Vol. 40, No. 4, pp. 135-141 (July-August 1986)			
	BG	WILLIAMS et al., "Vial Breakage by Frozen Mannitol Solutions: Correlation with Thermal Characteristics and Effect of Stereoisomerism, Additives, and Vial Configuration," <i>Journal of Parenteral Science & Technology</i> , Vol. 45, No. 2, pp. 94-100 (March-April 1991)			
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Examiner Signature	Date Considered	

^{*} A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

⁺ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).